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**SECTRA**

Department of Health and Human Services  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Pre-Market Notification Section

16 August 1996

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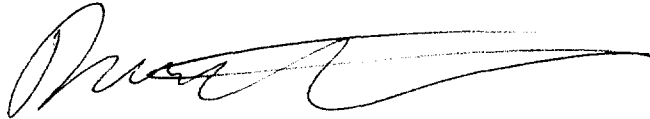
**510(k) summary of safety and effectiveness information for the SECTRA ImageServer  
2000 Picture Archiving System**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The ImageServer 2000 System will be used for digitally store images for archival together with informaton about the images. The typical users are trained medical professionals at a radiology department.

The undersigned certifies that the 510(k) Pre-Market Notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence to Olicon Imaging Systms, Inc. (K922164). This information and data is summarized as follows:

1. The ImageServer system is subject to and in compliance with the Federal Performance Standards, defined in 21 CFR, part 1000.
2. The ImageServer system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
3. The ImageServer User's Guide contains comprehensive and extensive information on how to operate the system to ensure a safe and effective use.
4. The submission contains the results of an hazard analysis.



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